

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
28 March 2002 (28.03.2002)

PCT

(10) International Publication Number  
**WO 02/24088 A2**

(51) International Patent Classification<sup>7</sup>: **A61B 17/72**

(21) International Application Number: **PCT/US01/27556**

(22) International Filing Date:  
6 September 2001 (06.09.2001)

(25) Filing Language: **English**

(26) Publication Language: **English**

(30) Priority Data:  
09/668,941 22 September 2000 (22.09.2000) **US**

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(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Published:**

— without international search report and to be republished upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: **INTRAMEDULLARY INTERLOCKING FIXATION DEVICE FOR THE DISTAL RADIUS**

(57) Abstract: Methods and devices for treating fractures in or adjacent the wrist and distal forearm employ an intramedullary interlocking fixation rod (i.e. it interlocks the distal and proximal fracture fragments together) to stabilize the skeletal structure in a manner which can inhibit the amount of collapse or loss in skeletal length exhibited by a patient with a distal radius fracture.

WO 02/24088 A2

## INTRAMEDULLARY INTERLOCKING FIXATION DEVICE FOR THE DISTAL RADIUS

### Field of the Invention

This invention relates to devices and methods for treating distal radius fractures.

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### Background of the Invention

Distal radius fractures are among the most common type of bone fracture of the upper extremities. The distal radius fracture is often called a "Colles" fracture (named after a 19<sup>th</sup> Century British surgeon who described the fracture). The Colles fracture is associated with a fracture of a distal tip or distal end portion of the radius.

Distal radius fractures are, unfortunately, most common in the elderly segment of the population. This is because the elderly tend to exhibit some degree of bone density loss or osteoporotic condition making their bones more susceptible to injury. Indeed, just as osteoporosis is known to affect women more often and more severely than men, distal radius fractures are much more common in females than males, typically on the order of about 20:1. Distal radius fractures generally occur as a result of a fall, because the patient tends to brace for the fall by outstretching the hand which then fractures upon impact, at the distal radius at or adjacent the wrist.

As shown in Figures 1 and 2, the distal radius fracture is such that the major fracture line 15 associated with this type of injury generally occurs just above or proximal to the articular joint surface 11 of the distal radius at the wrist about the metaphysis 12. As shown in Figures 1 and 2, one common distal radius fracture type separates the shaft 13 of the radius 10 from the distal end portion of the bone. That is, the fracture line 15 defines a first major bone fragment 18 which is located distal to the fracture line 15 proximate the articular joint surface 11 and extends substantially

medially (laterally) across the radius 10 in the metaphysis region. Although not shown, the fracture may also produce smaller bone fragments or splinters along the fracture line. Further, the distal end portion of the radius may be present as multiple (vertically and/or horizontally oriented) fragments disrupting the articular joint surface itself. This latter type of Colles fracture is known as a comminuted intraarticular fracture (not shown).

Figure 1 illustrates the fracture line 15 in the radius 10 as a substantially horizontal line which produces an upper or distal fracture fragment 18 as a substantially unitary fragment. Similarly, Figure 2 illustrates a fracture line 15 in the radius 10 which is offset from a horizontal axis.

Distal radius fractures can be difficult to treat, particularly in the older osteoporotic patient. Conventionally, this type of fracture has been treated by a closed (non-surgical) reduction and application of a splint (such as a plaster compression dressing) or a cast (typically circular plaster or fiberglass). Unfortunately, primarily because of the patient's osteoporosis, during the healing process, and despite the splint/cast immobilization, the fracture fragments can settle, potentially causing a collapse at the fracture line in the distal radius. Figure 2 illustrates a loss of radial inclination (in degrees) and a shortened length in the skeletal length line (shown with respect to a neutral length line "L") which can occur after a fracture in the distal radius. That is, even healed, these types of fractures may cause shortening or collapse of the bone structure relative to the original skeletal length line. This, in turn, can result in deformity and pain.

Treatment options for a collapsed distal radius fracture are relatively limited. The primary conventional treatments include the use of devices which can be characterized as either external fixation devices or internal fixation devices. External fixation devices are those that stabilize a fracture through the use of percutaneous pins which typically affix one or more bone portions to an external (anchoring or stabilizing) device. Internal fixation devices are those devices which are configured to reside entirely within the subject (internal to the body). Percutaneous pins can be used alone, without anchoring devices, for fixation of Colles type fractures. The use of external devices has conventionally been thought to be particularly indicated in cases of bone loss to preserve skeletal length as noted, for example, in U.S. Patent No. 5,571,103 to Bailey at col. 1, lines 35-43. However, such devices can be bulky,

cumbersome, and or invasive to the user or patient. Further, the external fixation devices may not be suitable for use in soft osteoporotic bone.

In view of the foregoing, there remains a need for improved distal radius fracture treatment devices and techniques.

5

### Summary of the Invention

In a preferred embodiment, the present invention provides methods and devices for treating fractures in or adjacent the wrist and distal forearm. The present invention is particularly useful for stabilizing and treating distal radius fractures of a patient. The devices and methods of the present invention employs an intramedullary interlocking fixation rod (*i.e.*, it interlocks the distal and proximal fracture fragments together) to stabilize the skeletal structure in a manner which can inhibit the amount of collapse or loss in skeletal length exhibited by a patient with a distal radius fracture. The devices and methods of the present invention may be especially useful for treating distal radius fractures in subjects with osteoporosis.

15 One aspect of the invention is a method for treating a distal radius fracture of a patient comprising the use of an internal fixation rod. As noted above, the radius anatomically has an articular joint surface, a metaphysis region, a shaft portion and a medullary canal associated therewith. The distal radius fracture has a fracture line which divides the radius into a distal fracture fragment portion and a proximal fracture fragment portion. The distal fragment portion includes the distal end of the radius proximate the articular joint surface, and the distal portion of the fracture has a width thereacross. The method comprises the steps of: (a) installing an elongated rod having opposing proximal and distal portions into the medullary canal of the patient such that the proximal portion of the rod resides above the fracture line (closer to the elbow) and the distal portion of the rod resides below the fracture line (closer to the hand); (b) securing a distal fixation member to the elongated rod and into the distal end portion of the radius at a location which is below the fracture line such that the distal fixation member extends internal of the patient substantially laterally across a portion of the width of the distal fracture fragment; and (c) anchoring the elongated rod inside the medullary canal of the radius at a location which is above (distal to) the fracture line.

Another aspect of the present invention is an internal fixation device for treating or repairing distal radius fractures having a fracture line forming distal and proximal fracture fragments. The radius is anatomically configured with a distal articular joint surface, a metaphysis region, a shaft, and a medullary canal. The anatomic position of the hand is palm forward or front such that the medial orientation is next to the body (fifth finger or ulna side of hand) and the lateral orientation is away from the body (thumb or radial side). Generally stated, the distal portion of the radius has a width which extends across (a major portion of) the arm from the medial side to the lateral side. The device includes an elongated fixation rod having opposing proximal and distal portions. The distal portion includes a head with a laterally extending distal aperture formed therein, and the proximal portion comprises at least one proximal aperture formed therein. The elongated fixation rod proximal portion is sized and configured such that, in position, it resides in the shaft inside a portion of the medullary canal of the radius of a patient. The device also includes a distal fixation member configured to enter the distal aperture and attach to the rod and the distal fracture fragment to hold the distal portion of the rod to the distal fracture fragment. The device further includes at least one proximal fixation member, a respective one for each of the at least one proximal apertures. The proximal fixation member is configured to secure the lower portion of the fixation rod to the radius at a position which is distal to the fracture line. In position, the elongated fixation rod is configured to reside within the radius, and the distal fixation member and the at least one proximal fixation member are configured to reside internal of the body of the patient.

In a preferred embodiment, the elongated fixation rod has a curvilinear profile. The curvilinear profile includes a distal curve portion at the distal portion of the device. The distal curve portion is adapted to accommodate the radial styloid region of the radius proximate the articular joint surface. The rod can also be provided as a plurality of segments matable or attachable. In one embodiment an intermediate segment can be provided in different lengths to allow for the adjustment of length according to a patient's anatomical considerations. Of course, the rod can be a unitary body provided in a number of standard sizes preferably statistically representative of the treatment population.

The foregoing and other objects and aspects of the present invention are explained in detail in the specification set forth below.

#### Brief Description of the Drawings

5        **Figure 1** is an anterior-posterior view of a distal radius fracture illustrating a fracture line proximate the articular joint surface.

**Figure 2** is an anterior-posterior view of a distal radius fracture similar to that shown in **Figure 1**. This figure illustrates an alternatively configured fracture line proximate the articular joint surface.

10       **Figure 3A** is an anterior-posterior view of an intramedullary fixation rod attached to the radius for treating a distal radius fracture according to an embodiment of the present invention.

**Figure 3B** is an exploded view of the distal fixation attachment member shown inserted into the fixation rod in **Figure 3A** according to one embodiment of the  
15       present invention.

**Figure 4** is a front schematic view of the distal fixation rod of **Figure 3A** in position as an internal fixation device held within the body of the patient according to one embodiment of the present invention.

**Figure 5A** is a lateral view of an intramedullary rod configured to interlock or  
20       affix the bone fragments of a distal radius fracture according to one embodiment of the present invention.

**Figure 5B** is a cross-sectional view of the rod shown in **Figure 5A** taken along line 5B-5B.

**Figure 6** is a perspective view of an intramedullary fixation device according  
25       to one embodiment of the present invention.

**Figure 7** is a side view (shown oriented anterior to posterior) of an alternate embodiment of an intramedullary system according to the present invention.

**Figure 8** is a side view (shown oriented anterior to posterior) of another embodiment of an intramedullary system according to the present invention.

30       **Figures 9A** is a front anterior-posterior view of an alternate embodiment of a distal fixation rod according to the present invention.

**Figure 9B** is an exploded view of the linked or multi-segment rod shown in **Figure 9A**.

Figure 9C is a front view of a set of intermediate rod segments according to an embodiment of the present invention.

Figure 10 is a schematic side view of an intramedullary system with an external detachable positioning guide according to an embodiment of the present invention.

Figure 11 is a block diagram of the steps of treating a distal radius fracture according to one embodiment of the present invention.

Figure 12 is perspective view of the arm of a patient illustrating a sigmoid or longitudinal incision over the radial styloid area.

Figure 13 is an enlarged schematic view of the incision site in the patient shown in Figure 12 to illustrate preparation of the site for positioning intramedullary fixation rods for distal radius fractures according to an embodiment of the present invention.

Figure 14 is an enlarged schematic view of the incision site shown in Figure 13 illustrating that a small bone window may be made or formed into the radius such that it extends across the fracture site according to the present invention.

Figure 15A is an anterior-posterior view of the bone window shown in Figure 14.

Figure 15B is a schematic view of the prepared bone site shown in Figure 15A illustrating the use of a sound or broach instrument which is sized and configured to be inserted into the intramedullary canal of the radius to determine size and/or open or prepare the canal to receive a fixation rod according to an embodiment of the present invention.

Figure 16 is a top anterior-posterior view of an intramedullary fixation rod assembled to a rod driver and screw attachment guide according to one embodiment of the present invention.

Figure 17 is a side (lateral) view of the device shown in Figure 16.

Figure 18 is a side of the device shown in Figures 16 and 17 showing the device in position in the patient.

Figure 19 is a top anterior-posterior view of the device shown in position in Figure 18.

Figure 20 is a schematic view of the fixation rod in position in the subject according to an embodiment of the present invention.

### Description of Preferred Embodiments

The present invention will now be described more fully hereinafter with  
5 reference to the accompanying figures, in which preferred embodiments of the  
invention are shown. This invention may, however, be embodied in many different  
forms and should not be construed as limited to the embodiments set forth herein.  
Like numbers refer to like elements throughout. In the figures, certain layers, regions,  
or components may be exaggerated for clarity.

10 As shown in **Figure 3A**, in a preferred embodiment, the intramedullary  
fixation device 25 includes an elongated axially extending rod 26 with a distal portion  
27 and a proximal portion 28. The device 25 also includes a distal fixation member  
30 and at least one proximal fixation member 35 (shown as two proximal fixation  
members 35a, 35b). The rod 26 includes a head 26h at the distal end portion 27 of  
15 the rod 26. A distal aperture 30a is formed into the head 26h of the distal portion  
such that it extends across the width of the rod 26.

As shown, the distal fixation member 30 is configured to enter and extend  
through and beyond the distal aperture 30a to engage with the distal fracture fragment  
18 and secure the rod 26 and the distal fracture fragment 18 theretogether. Preferably,  
20 the distal fixation member 30 is sized to extend across a major portion of the width of  
the distal fracture fragment 18. More preferably, the distal fixation member 30 is  
sized with a length which is sufficient to extend across substantially all of the fracture  
fragment 18 so as to provide support for the radial, center, and ulna aspects of the  
distal fracture fragment 18 (the ulna aspect being the part of the fracture fragment  
25 adjacent or proximate the ulna 14 while the radial aspect being the portion of the  
fracture fragment on the opposing side of the view shown in **Figure 3A** and the center  
aspect being the portion in between).

**Figure 3B** illustrates the distal fixation member 30 apart from the rod 26. The  
distal fixation member 30 can be configured as any suitable attachment means to  
30 secure the distal fracture fragment 18 to the rod 26, while also providing lateral  
structural reinforcement. For example, but not limited to, the attachment means can  
be one or more of a pin, nail, threaded or partially threaded member such as a screw,  
or a combination of the above. **Figure 3B** illustrates the distal fixation member 30 as



having, in serial order, from one end to the other, a head portion 30h, a threaded portion 30th, and a pin portion 30p.

In one embodiment, as shown in Figure 3A, the head of the distal fixation member 30h extends beyond the edge of the body of the rod 26. However, as schematically shown in Figure 7, the aperture 25a can be configured (such as with a countersunk or recessed portion configured with a depth sufficient to receive the head 30h therein) such that upon assembly, the distal fixation member head 30h is substantially flush or recessed with the outer contour or profile of the rod 26. Figure 3A also illustrates that, in position in the patient, the distal fixation member 30 is preferably configured to directly abut the outer surface of the rod 26. Figure 6 is a perspective view of one embodiment of the intramedullary fixation device 25. This embodiment shows that the rod 26 is configured as a unitary body with a recess to receive the head 30h of the distal fixation member 30.

In a preferred embodiment, the rod 26 is configured with a profile 26p which is curvilinear when viewed from the anterior-posterior view, as shown, for example, in Figures 3A and 4. As shown, the proximal portion of the rod 28 is substantially linear and is configured to axially extend within the medullary canal of the patient in the radial shaft. As the rod 26 approaches the metaphysis region (12, Figure 1) it gradually curves from the substantially linear axial extending portion so as to position the distal end 27e of the rod 26 proximate the radial styloid region of the distal radius. Preferably, the rod 26 is configured to follow the contour line of the radius as it transitions from the proximal portion 28 having a substantially linear contour in the shaft region to the distal portion 27 which has a curvilinear or slight arcuately contoured shape proximate the metaphysis region.

Figures 3A and 4 also illustrate that the head 26h of the rod 26 is preferably configured with a body which has an increased perimeter or area size with respect to the proximal 28 portion of the rod 26. It is also preferred that the distal end of the head 26h be beveled or inclined 27i. As shown, the tip or end of the head 26h slopes downwardly from the side surface adjacent the radial portion toward the ulna aspect of the fracture fragment 18.

It is additionally preferred that the distal aperture 30a be formed in the rod 26 such that it allows the distal fixation member 30 to extend therethrough and reside at a position which is angularly offset from the axial axis. As shown in Figure 3A, the

axial axis is coincident with the centerline of the proximal portion of the rod (indicated by the letter "a" in Figure 3A). Preferably, the distal fixation member 30 extends at a position which is less than about ninety degrees, and preferably between about 10 degrees to less than about 90 degrees, away from the axial axis, such that it is approximately in-line with the articular surface.

In this embodiment, the head 26h of the rod 26 can buttress the distal radius region and increase the structural effectiveness of the rod. Thus, together with the proper positioning of the distal portion 27 of the rod 26 in the distal radius and/or the medial extension of the distal fixation member 30, the head 26h, can reinforce or positively affect the structural integrity of the device to help support the radial styloid region of the distal fracture fragment.

Referring again to Figure 3A and Figure 4, at least one, and preferably two or more, proximal fixation members 35 are used to secure the rod 26 to the shaft region 13 of the radius 10 at the lower or proximal portion of the rod 26. Figure 3A illustrates the use of two similarly sized proximal fixation members 35a, 35b, respectively, while Figure 4 illustrates the use of one 35. Preferably, as shown in Figure 5A, the proximal fixation members 35a, 35b are respective self-tapping screws positioned on the rod 26 such that they are proximate to each other. However, pins, nails, or other attachment means (as well as numbers and positioning of same) can also be used as will be appreciated by one of skill in the art. It will be appreciated, by those of skill in the art, that the proximal fixation members 35 and corresponding apertures 25a are primarily used to inhibit shortening of the skeletal structure. As shown in Figure 5A, the proximal fixation member 35 transversely extends in serial order, through a portion of the radius shaft, through a corresponding proximal receiving aperture 25a formed in the rod 26, and then into an opposing portion of the radius shaft to thereby secure or locate and hold the proximal portion of the rod 25 relative to the radius, the proximal fixation member having a length and opposing ends sized and configured accordingly 36, 38.

Figure 4 schematically illustrates the preferred post-operative position of the intramedullary fixation device 25 in the patient. That is, post-operatively in position in the patient, the rod 26 and distal and proximal fixation members 30, 35 are held within the body of the subject such that the device 25 is an internal fixation device and is devoid of externally located coupling or fixation members.

As shown in Figure 4, the rod 26 is installed into the medullary canal of the patient such that the distal portion 27 of the rod 26 resides distal to the fracture line 15 (but substantially within the distal radius, preferably so as to reside proximal to the articular joint surface 11) and the bottom or proximal portion 28 of the rod 26 extends through and resides proximal to the fracture line 15. The distal fixation member 30 is secured to the rod 26 and to the distal end portion of the radius at a location which is distal to the fracture line 15 in the metaphysis region of the distal radius. As is also shown, the distal fixation member 30 extends (to reside internal of the body of the patient) substantially transversely across a portion of the width of the distal fracture fragment 18. The device 25 may not be preferred for use with comminuted distal radius fractures.

In position, the rod 26 is configured such that it also extends through a portion of the medullary canal to terminate therein in the shaft region 13 of the radius 10 (Figure 1) (at a location which is proximally spaced away from the fracture line 15). The proximal portion 28 of the rod 26 is anchored to the radius so as to reside inside the medullary canal of the radius. The proximal portion 28 of the rod 26 is fixed in position relative to the shaft of the radius by the use of at least one pin, screw, or the like, as discussed above. As is also noted above, it is more preferred that two (and potentially three or more) to provide increased structural stability so as to inhibit the propensity of the rod 26 to toggle or move distally with the distal fragment.

Figure 4 also illustrates that the proximal end of the rod 28e may be configured with a reduced cross-sectional size or tapered perimeter relative to the portion of the rod 26 thereabove to allow for ease of insertion into the patient. Preferably, as shown, the proximal end of the device 28e is substantially pointed.

Figure 5A illustrates the rod 26 with a length "L", a width "W" and a thickness "T". It is envisioned that the rod 26 be provided or be made available for use in a plurality of lengths and widths so that the clinician can select the appropriate dimensions according to the particular anatomical needs of the patient. Preferably, for the distal radius fracture, the length of the rod 26 is between about 2-5 inches long, and more preferably between about 2.5 inches - 4.0 inches long. It is also preferred that the width of the rod 26 be provided in an arrangement of incremental sizes. It is thought that suitable widths may be between about 2-8mm in width and more preferably between about (2.5-4mm) in width.

As shown in Figure 5B, the rod 26 is held in the medullary canal of the radius of the patient. The lower or proximal portion 28 of the rod 26 is preferably held substantially centrally in the shaft portion 13 of the radius 10. In one embodiment, the cross sectional shape of the rod 26 is rectangular. The rod 26 can be configured with other cross-sectional shapes, such as, but not limited to, circular, oval, square, triangular, and hexagon. It is also preferred that in designs with sharp edges, that the edges be radiused ("break edges") to reduce the likelihood of stress fractures in the rod 26 (or in the bone adjacent the rod). Further, the distal portion 27 of the rod 26 may have a different cross-sectional shape and configuration from the proximal portion 28 of the rod 26. For example, the proximal portion 28 of the rod 26 may have a circular shape with the addition of a ribbed portion on one side to inhibit rotation once in the intramedullary canal in the radius of the patient, while the distal portion 27 of the rod 26 can have an oval or rectangular shape (not shown).

Figure 7 illustrates another embodiment of an intramedullary fixation device 25' according to the present invention. In this embodiment, the rod 26 is configured as first and second attachable segments or links 127, 128. As shown, the distal segment 127 of the rod 26 is configured with the head of the rod 26h while the proximal portion 128 is again configured to reside in the medullary canal of the radius shaft. The two segments 127, 128 are configured to align and mate together to define the rod 26. As shown in Figure 7, a linking screw 120 is inserted into a threaded aperture 120a that it spans the first and second segments 127, 128 when aligned. Of course, other attachment means or segment link configurations can also be used, such as, but not limited to, bayonet type fittings, friction fit or threaded matable female/male components, and the like.

Figure 8 illustrates another embodiment of an intramedullary fixation device 25'' for the radius according to the present invention. In this embodiment, the rod 26 includes a proximal extension 28ext. As shown, the proximal extension 28ext is tapered adjacent the proximal end portion 28 of the rod 26. The extension 28ext is configured to reside in a more proximal portion of the radius shaft (away from the hand and closer to the elbow). This embodiment may also be used in the absence of a distal radius fracture to treat proximal radius fractures. Figure 8 also illustrates that the distal fixation member 30 is oriented at about 45 degrees with respect to the axial

axis. In any event, this configuration can allow for additional support in the shaft region of the radius (*i.e.*, more proximal "purchase").

Figure 9A illustrates a rod 26 having a body with multiple segments or links 127', 129, 128'. As shown, in this embodiment, the rod 26 is defined by three segments, the distal segment 127', an intermediate segment 129, and a proximal segment 128'. Figure 9B illustrates that, in this embodiment, the distal segment 127' includes a protrusion 127p' while the upper portion of the intermediate segment 129 includes a recess 129r configured and sized to matably and/or securely receive the protrusion 127p' therein. Similarly, the proximal segment 128' includes a recess 128r' formed therein configured to receive the intermediate segment protrusion 129p therein. Preferably, the segments 127', 129, 128' are sized and configured to be held together by a frictional fit of the interlocking or mating components, however, a biocompatible adhesive can also be used, as desired. Other attaching means can also be used to secure the segments together as will be appreciated by those of skill in the art. For example, the protrusion 127p' can be threaded and configured to threadably engage with a threaded recess 129r formed in the upper portion of the intermediate segment 129. Similarly, the proximal recess 128r' can be threaded and configured to threadably engage with the intermediate segment 129p protrusion (which can be configured as a correspondingly configured male threaded component).

As shown in Figure 9C, the intermediate segment 129 can be provided in an assortment of lengths to allow the rod 26 to be adjusted to a desired length according to the anatomical considerations of the patient. Alternatively, the intermediate segment 129 can be a plurality of similarly sized or different, incrementally sized segments. In this way, the distal and proximal segments 127', 128' can be provided as standardized-length components with the intermediate segment 129 providing an adjustable length. Thus, the clinician can custom fit the rod 26 at the use site. That is, the clinician can assess the patient and then determine the appropriate number or size of intermediate segments 129 to be used dependent on the length desired. This custom fit does not require the use of a preformed rod or a special order rod. Rather, the fit can be carried out at the clinic, use, or installation site (proximate in time or contemporaneous with the treatment) to fit the number and size components together according to the needs of the patient. Alternatively, the distal and/or proximal

segments 127', 128' can also (or alternatively) be configured as or provided in different lengths.

Figure 10 illustrates the use of an insertion or positioning guide 150 affixed to the distal end portion 27 of the rod 26 to allow for ease of insertion and placement into the patient. As shown, the guide 150 includes an axially (or longitudinally) extending arm 151 which is configured to reside external of the body of the patient when the rod 26 is inserted into the intramedullary canal. As is also shown, the guide arm 151 includes a visual locating means or visual indicia 153, 155 which correspond to the proximal fixation apertures 25a<sub>1</sub>, 25a<sub>2</sub> to mark or identify the location of the internal apertures when the rod 26 is in a desired position in the patient. This allows the physician to be able to insert the proximal fixation members 35a, 35b in the proper location, aligned with the proximal apertures on the rod 26 held inside the patient.

As shown, the visual indicia 153, 155 is preferably provided as laterally extending drill guides 153, 155 which act to support a drill as it enters the patient and allows the drill to be inserted therein and guided to the desired location to provide bores into the bone on opposing sides of the rod 26 that are aligned with the rod proximal fixation apertures 25a<sub>1</sub>, 25a<sub>2</sub>.

Referring to Figure 12, generally described, to position the intramedullary fixation rod 26 into the patient, an incision is made, such as a sigmoid or longitudinal incision over the radial styloid region of the patient's arm (adjacent to the base of the thumb). As shown in Figure 13, dissection is carried down to the interval between the first and second dorsal compartments. Care should be taken so as not to injure the branches of the dorsal radial nerve. A small area of exposed bone is present between the first and second compartments (typically covered only by periosteum). As shown in Figures 14 and 15A, a small bone window 16 is preferably formed or made into the radius in this area. It may be appropriate to elevate the sheaths of the first and second dorsal compartments to facilitate adequate exposure for the bone window 16. Although shown as a substantially rectangular bone window, other shapes may also be used to provide access to the fracture region.

As shown in Figure 15B, a finder, sound, or broach-like device 175 can be used prior to inserting the fixation rod 26 into the patient. The device 175 is preferably semi-flexible to follow the contour of the canal in the radius. The device

175 can be inserted through the bone window 16 and about the fracture region and used to determine the size and length of the intramedullary canal and/or to open the canal to a size suitable for receiving the fixation rod 26. The sounds are available in length-and width calibrated sizes to help determine a size and length suitable for the  
5 fixation rod 26 according to the particular patient's intramedullary canal structure. As such, the device 175 can bore out or ream and/or define a desired entry and insertion passageway for the device 25, 25', 25'' in advance of an actual installation into the patient. A fluoroscopic evaluation technique can be used to visualize the insertion of the device 175 and can help determine if the canal needs to be enlarged with a reamer  
10 or if a insertion path needs to be formed or shaped.

After the appropriate size and length fixation rod 26 is selected, the rod can be attached to an insertion guide device 150, 150'. Figure 10 illustrates one embodiment of a guide 150. As shown, an applicator/handle or driver 150 is attached to the rod 26 into the distal aperture 30a). The handle or driver 150 then allows the  
15 physician to insert and guide the rod 26 into the desired location in the medullary canal in the radius. Once the head 26h of the rod 26 is positioned below the articular joint surface, in its desired location in the distal radius, the proximal fixation members 35 (35a, 35b) are ready for insertion. Preferably, a small incision (or two) is made at the proximal site of the radius. A drill or driver is inserted into the locator or drill  
20 guide holder 152 to align the entry of the proximal fixation member about the proximal aperture 25 and then force the threaded proximal fixation member(s) 35 (35a, 35b) through the bone on the first (dorsal) side of the shaft of the radius, through the rod aperture 25a<sub>1</sub> (25a<sub>2</sub>) and into the bone on the opposing (volar) side of the radial shaft. Preferably, the proximal fixation member 35 (35a, 35b) extends

Figures 16 and 17 illustrate an additional embodiment of an insertion guide 150'. In this embodiment, the device 150' includes a rod driver 250 and an interlocking screw attachment guide 151'. Once the proper rod size is identified, the rod 26 is attached to the rod driver 250. The rod driver 250 is attached to the fixation rod 26 via the distal aperture in the head of the rod 26 and an associated attachment member (shown as a screw 30a) and the interlocking screw attachment guide 151' is attached to the rod driver 250. As for the other guide embodiment described above, the interlocking screw attachment guide 151' provides a screw guide alignment means such as screw or pin portals 153, 155 to facilitate proper orientation and location of the proximal screws or pins into the patient and into the shaft 25 of the fixation rod 26. Thus, in this embodiment, the span of the screw attachment guide 151' is configured to provide the proper alignment position relative to the rod driver 250.

As shown in Figures 18 and 19, the rod driver 250 of the insertion guide 150' is used to direct the rod 26 into the intramedullary canal of the patient. The rod driver 250 allows a physician to direct the fixation rod 26 into the radius through the bone window 16. The position of the rod and the reduction of the fracture can be verified by a fluoroscopy unit. Once the rod 26 is in position, a small incision can be made so that the proximal attachment guides 153, 155 can be inserted therein. Traction may be appropriate to reduce the fracture at this time. The proximal attachment members 35a, 35b can then be inserted into the radius after the region has been drilled and/or tapped. Again, the proper positioning of the proximal attachment members 35a, 35b, can be verified by the fluoroscopy unit. The interlocking screw attachment guide 151' can then be removed from the patient and the rod driver 250. The rod driver 250 can be detached from the fixation rod 26 and the distal fixation member 30 can be inserted into the distal fragment and the fixation rod 26 as shown in Figure 20.

Routine closure is performed on the incision sites and then, preferably, a long arm cast is applied to the patient. The typical healing process is about six weeks, during which time it is preferred that the treatment area be protected from undue stress and activity.

A rod according to the present invention can be formed from a number of suitable biocompatible materials including titanium, stainless steel, and cobalt chrome. Because the radius is not a weight bearing extremity, strength is not as important in this type of fixation rod as it might be in other fixation rod applications.



Surface coatings may also be used as appropriate. For example, as the device 25, 25', 25'' chronically resides in the body, surface or other treatments may also be applied to, or integrated into, the rod 26 and/or the fixation members 30, 35 to achieve one or more of increased lubricity, low coefficient of friction (each for easier insertion) as well as increased tissue biocompatibility such as resistance to microbial growth and/or configured to reduce the incidence of inflammation or infection during healing. In one embodiment, the rod 26 comprises a material, at least on its exposed surfaces, which can inhibit the growth of undesirable microbial organisms. Preferably, the rod is coated with a biocompatible antimicrobial solution or coating which can inhibit the growth of bacteria, yeast, mold, and fungus. One suitable material may be the antimicrobial silver zeolite based product available from HealthShield Technologies LLC of Wakefield, MA. Another alternative is a Photolink® Infection Resistance antimicrobial coating or a hemocompatible coating from SurModics, Inc. of Eden Prairie, MN. The coating may also include other bioactive ingredients (with or without the antimicrobial coating), such as antibiotics, and the like. One product is identified as LubriLAST™ lubricious coatings from AST of Billerica, MA.

In addition to, or alternatively, a rod according to the present invention can be configured with a biocompatible lubricant or low-friction material to help reduce any discomfort associated with the insertion of the device into the body. Coatings which may be appropriate include coatings which promote lubricity, and wettability. For example, a hydrophilic coating which is applied as a thin (on the order of about .5-50 microns thick) layer which is chemically bonded with UV light over the external surface of the rod 26. One such product is a hydrophilic polymer identified as Hydrolene® available from SurModics, Inc., of Eden Prairie, MN. Other similar products are also available from the same source. Still further, the rod 26 can be configured not only to provide the lubricious coating but to also include bioactive ingredients configured to provide sustained release of antibiotics, antimicrobial, and anti-restenosis agents, identified as LubriLast™ from AST as noted above.

**Figure 11** illustrates the steps of a method for treating a fracture in the radius of a patient according to one embodiment of the present invention. An elongated axially extending rod is inserted into the intramedullary canal of the patient (Block 210). Proximal fixation members are then secured to the rod to hold the rod in the

intramedullary canal attached to the proximately located bone in the radius shaft (Block 220). A distal fixation member is inserted into a distal portion of the rod such that it extends substantially medially or transversely across a distal portion of the radius (Block 230). A bone window may be formed into the radius to define an entry point for the rod (typically the window is formed into a small area of exposed bone which is present between the first and second compartments and covered only by periosteum) in the styloid region adjacent the two bone fragments.

The internal intramedullary radius fixation devices and associated treatment methods of the instant invention can provide improved or alternative treatment options over those conventionally available. The devices and methods of the instant invention may inhibit the collapse in the skeletal structure along the fracture fragment region and may be useful for the osteoporotic patient. The devices of the instant invention can also provide increased structural integrity and/or strength when in position in the distal radius fracture fragment.

The foregoing is illustrative of the present invention and is not to be construed as limiting thereof. Although a few exemplary embodiments of this invention have been described, those skilled in the art will readily appreciate that many modifications are possible in the exemplary embodiments without materially departing from the novel teachings and advantages of this invention. Accordingly, all such modifications are intended to be included within the scope of this invention as defined in the claims. In the claims, means-plus-function clauses, if used, are intended to cover the structures described herein as performing the recited function and not only structural equivalents but also equivalent structures. Therefore, it is to be understood that the foregoing is illustrative of the present invention and is not to be construed as limited to the specific embodiments disclosed, and that modifications to the disclosed embodiments, as well as other embodiments, are intended to be included within the scope of the appended claims. The invention is defined by the following claims, with equivalents of the claims to be included therein.

## THAT WHICH IS CLAIMED IS:

1. A method for treating a distal radius fracture of a patient comprising the use of an internal fixation rod, the radius anatomically having an articular joint surface, a metaphysis region, a shaft portion and a medullary canal associated therewith, the distal radius fracture having a fracture line which divides the radius into  
5 a distal fracture fragment portion and a proximal fracture fragment portion, the distal fragment portion including the distal end of the radius proximate the articular joint surface, the distal portion of the fracture having a width thereacross, said method comprising the steps of:
  - 10 installing an elongated rod having opposing proximal and distal portions into the medullary canal of the patient such that the distal portion of the rod resides distal to the fracture line and the proximal portion of the rod resides proximal to the fracture line;
  - securing a distal fixation member to the elongated rod and into the distal end portion of the radius at a location which is distal to the fracture line such that the  
15 distal fixation member extends internal of the patient across a portion of the distal fracture fragment; and
  - anchoring the elongated rod inside the medullary canal of the radius at a location which is below the fracture line.
2. A method according to Claim 1, wherein said anchoring step includes the step of inserting, in serial order, at least one proximal fixation member into a first side of the shaft of the radius, into the elongated rod in the intramedullary canal, and then into the opposing side of the shaft of the radius.
3. A method according to Claim 2, wherein the at least one proximal fixation member is two.
4. A method according to Claim 1, wherein the elongated rod includes a respective one aperture formed therein for each of said at least one proximal fixation members.

5. A method according to Claim 4, wherein each proximal aperture is unthreaded and the proximal fixation members are configured to threadably attach to the radius shaft.
6. A method according to Claim 4, further comprising the steps of:  
attaching an external positioning guide onto a distal portion of the elongated rod such that the guide extends above the radius external of the patient's body to visually indicate the position of the at least one proximal aperture in the rod as it  
5 resides in the medullary canal of the patient; and  
removing the external positioning guide after said step of securing said at least one proximal fixation member to the rod and the radius.
7. A method according to Claim 1, wherein the elongated rod is configured, when viewed from an anterior-posterior direction, such that the rod substantially linearly extends along the proximal portion thereof and then transitions to take on a curvilinear profile adjacent the distal portion of the rod.
8. A method according to Claim 7, wherein said upper distal end portion of the rod has an increased cross-sectional area relative to the lower proximal portion.
9. A method according to Claim 1, wherein said upper distal end portion of the rod has a head which is beveled.
10. A method according to Claim 1, wherein said securing the distal fixation member to the elongated rod is carried out such that the distal fixation member extends internal of the patient substantially medially across a major portion of the width of the distal fracture fragment.
11. A method according to Claim 10, wherein said distal fixation member extends across substantially the entire width of the distal fracture fragment from the radial to ulnar regions to provide support for the central and ulnar aspect of the distal radius fragment.

12. A method according to Claim 10, wherein the distal fixation member angularly extends between about 10-90 degrees away from the axial direction defined by a line drawn through the center of the proximal portion of the elongated rod.

13. A method according to Claim 1, wherein at least a portion of said elongated rod has a cross section which is substantially rectangular.

14. A method according to Claim 1, further comprising the step of providing the elongated rod in an assortment of incremental sizes ranging from between about 2.5-4.5 inches long.

15. A method according to Claim 1, wherein, post-operatively in position in the patient, the elongated rod and fixation members are held within the body of the subject such that the rod and fixation members are devoid of externally located members.

16. A method according to Claim 1, wherein the distal fixation member extends across the distal fracture fragment in the metaphysis region of the distal radius.

17. A method according to Claim 1, wherein the elongated rod is configured with linkable segments.

18. A method according to Claim 1, wherein the elongated rod is a unitary body.

19. A method according to Claim 17, wherein the distal end portion of the elongated rod is matably attached to an intermediate portion of the rod.

20. A method according to Claim 17, wherein the elongated rod includes at least three matable segments, a distal end segment, a proximal end segment, and an intermediate length adjustable segment configured to attach said distal and proximal end segments together.

21. A method according to Claim 20, wherein the intermediate segment is provided in an assortment of lengths to adjust to the desired length of the rod to more appropriately fit the patient at a use or treatment point.

22. A method according to Claim 21, wherein the intermediate segment is a plurality of linkable similar sized segments for adjusting the desired length of the rod to reflect the patient's anatomical needs.

23. A method according to Claim 20, further comprising the step of selecting a desired length of the intermediate segment to correspond with the anatomy of the patient and attaching the intermediate segment to the distal end and proximal end segments.

24. A method according to Claim 23, wherein said selecting step is carried out substantially contemporaneous with said installing step.

25. An internal fixation device for treating or repairing distal radius fractures having a fracture line forming distal and proximal fracture fragments, the radius anatomically configured with a distal articular joint surface, a metaphysis region, a shaft, and a medullary canal, the distal portion of the radius having a width  
5 which extends from a radial region to a central and ulnar region, said device comprising:

an elongated fixation rod having opposing distal and proximal portions, said distal portion including a head with a laterally extending distal aperture formed therein, said proximal portion comprising at least one proximal aperture formed  
10 therein, wherein said elongated fixation rod proximal portion is sized and configured such that, in position, it resides in the shaft inside a portion of the medullary canal of the radius of a patient;

a distal fixation member configured to enter said distal portion aperture and attach to said rod and the distal fracture fragment to hold said distal portion of said  
15 rod to the distal fracture fragment; and

at least one proximal fixation member, a respective one for each of said at least one proximal apertures, said proximal fixation member configured to secure said proximal portion of said fixation rod to the radius proximal to the fracture line,

20 wherein, in position, said elongated fixation rod is configured to reside within the radius, and wherein said distal fixation member and said at least one proximal fixation member are configured to reside internal of the body of the patient.

26. A device according to Claim 25, wherein said elongated fixation rod has a curvilinear profile, said curvilinear profile including a distal curve portion at said distal portion of said device, said distal curve portion adapted to accommodate the radial styloid region of the radius proximate the articular joint surface.

27. A device according to Claim 26, wherein said head is configured with an increased perimeter relative to said rod proximal portion.

28. A device according to Claim 27, wherein said distal end of said head is configured such that it inclines downwardly across its width.

29. A device according to Claim 26, wherein said head flares to take on an increased width at said upper portion relative to said lower portion.

30. A device according to Claim 25, wherein said distal fixation member is configured to reside directly against said elongated fixation rod when in position in a patient.

31. A device according to Claim 25, wherein said proximal end portion has a smaller cross sectional area relative to a distal portion of said rod.

32. A device according to Claim 31, wherein said proximal end portion is configured as a tapered region.

33. A device according to Claim 25, wherein said at least one proximal fixation member is configured to attach to said elongated rod at a location which is

proximal to the fracture line and the metaphysics region such that, in position, said at least one proximal fixation member extends in serial order, through a portion of the radius shaft, through said proximal aperture in said rod, and then into an opposing  
5 portion of the radius shaft to thereby secure said proximal portion of said rod in position relative to the radius.

34. A device according to Claim 33, wherein each of said at least one proximal fixation members is configured to extend through said proximal aperture and threadably attach to the two portions of the radius shaft.

35. A device according to Claim 25, in combination with an insertion guide configured to removably attach to said distal portion of said rod at said distal aperture, said driver configured to allow positioning of said rod into the patient.

36. A device according to Claim 35, wherein said insertion guide comprises a longitudinally extending external proximal member alignment guide extending from at least said distal portion of said elongated rod to said proximal portion of said rod such that said proximal member alignment guide extends above  
5 the radius to visually indicate the position of said at least one proximal aperture in said rod as said rod resides in the medullary canal of the patient.

37. A device according to Claim 25, wherein said distal fixation member is secured to said elongated rod such that said distal fixation member extends internal of the patient substantially across a major portion of the width of the distal fracture fragment.

38. A device according to Claim 37, wherein said distal fixation member extends across substantially the entire width of the distal fracture fragment from the radial to ulnar regions to provide support the central and ulnar aspect of the distal radius fragment.

39. A device according to Claim 37, wherein, in position, said distal fixation member laterally extends at least about 45 degrees away from the axial



direction defined by a line drawn through the center of said proximal portion of said elongated rod.

40. A device according to Claim 25, wherein at least a portion of said elongated rod has a cross section which is substantially rectangular.

41. A device according to Claim 25, wherein said elongated rod is configured in an assortment of incremental sizes ranging from about 2.5-4.5 inches long and about 2.5-4 mm in width.

42. A device according to Claim 25, wherein, post-operatively in position in the patient, said elongated rod and distal and proximal fixation members are held within the body of the patient such that said device is devoid of externally located members.

43. A device according to Claim 25, wherein, in position, said distal fixation member extends across the distal fracture fragment in the metaphysis region of the distal radius.

44. A device according to Claim 25, wherein said elongated rod comprises a plurality of attachable segments.

45. A device according to Claim 44, wherein said elongated rod is configured as a unitary body.

46. A device according to Claim 44, wherein said elongated rod comprises a first distal segment providing said head portion of said rod and a second proximal segment providing said opposing proximal portion of said rod.

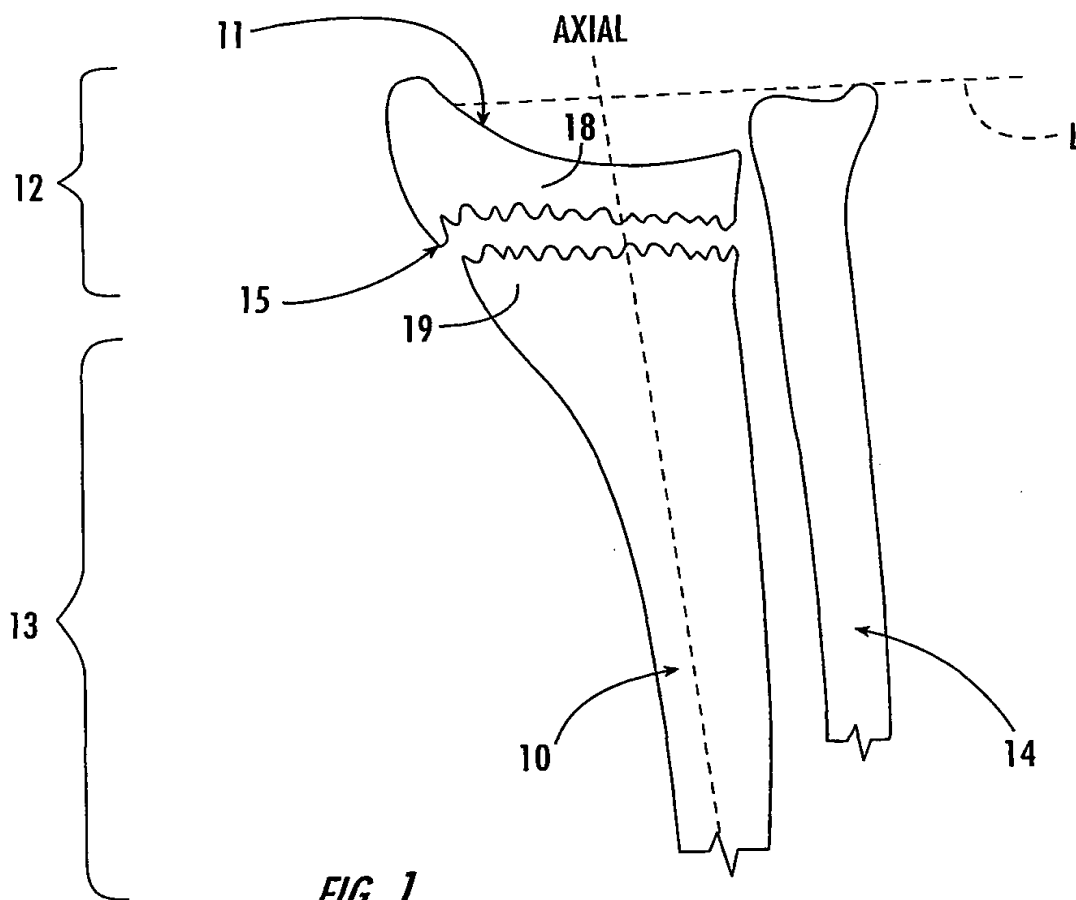
47. A device according to Claim 46, further comprising a threaded pin configured to engage with said first and second segments to hold said first and second segments in abutting alignment.

48. A device according to Claim 46, further comprising an intermediate segment with opposing upper and lower portions, wherein said upper portion is configured to matably attach to said first segment and said lower portion is configured to matably attach to said second segment.

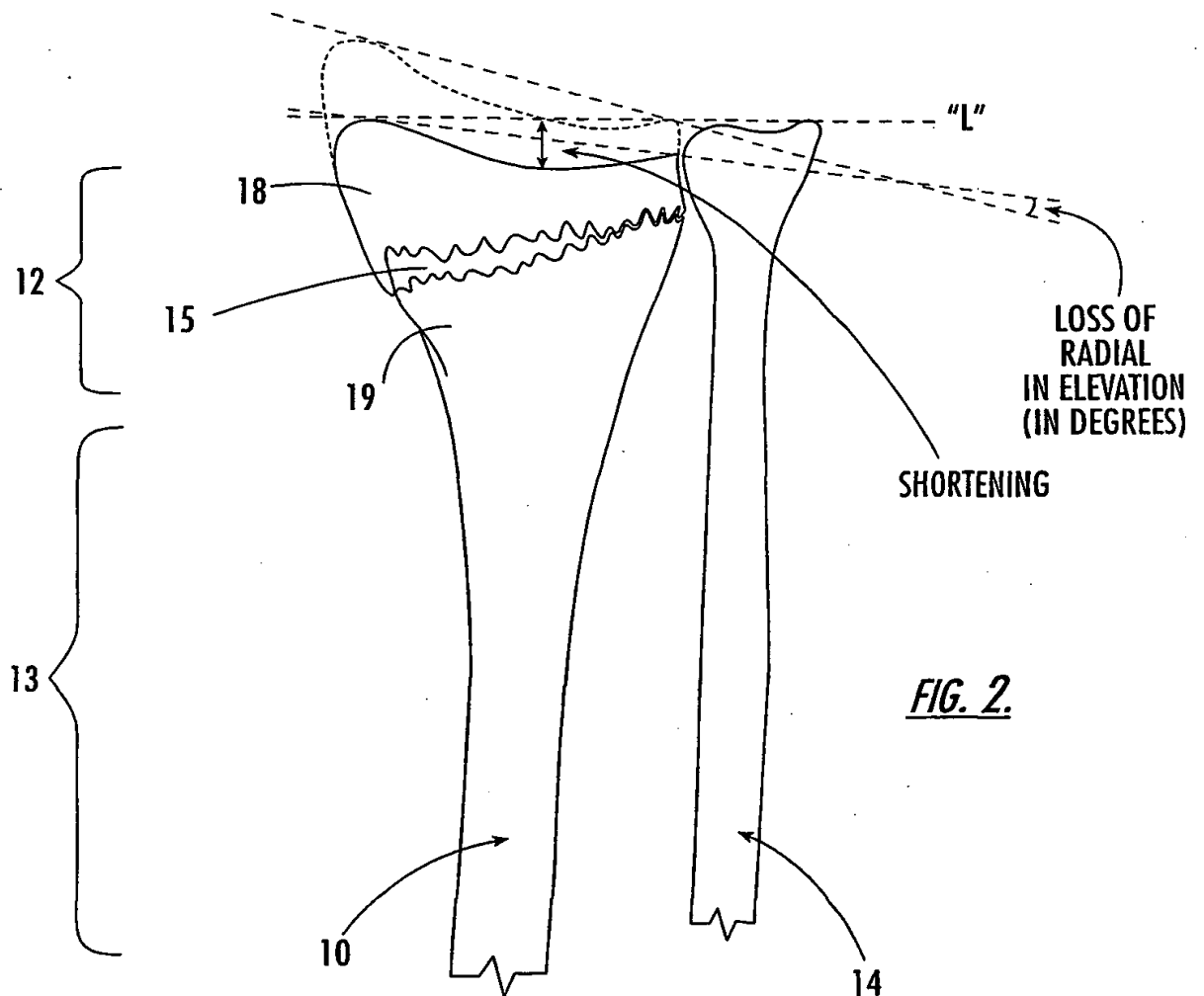
49. A device according to Claim 48, wherein said intermediate segment has a length which is selected to adjust the length of said rod.

50. A device according to Claim 49, wherein said intermediate segment is a plurality of linkable similarly sized segments for providing the desired length of the rod in order to correspond to the patient's anatomical considerations.

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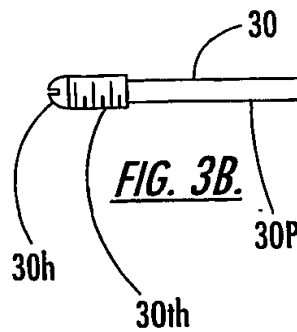
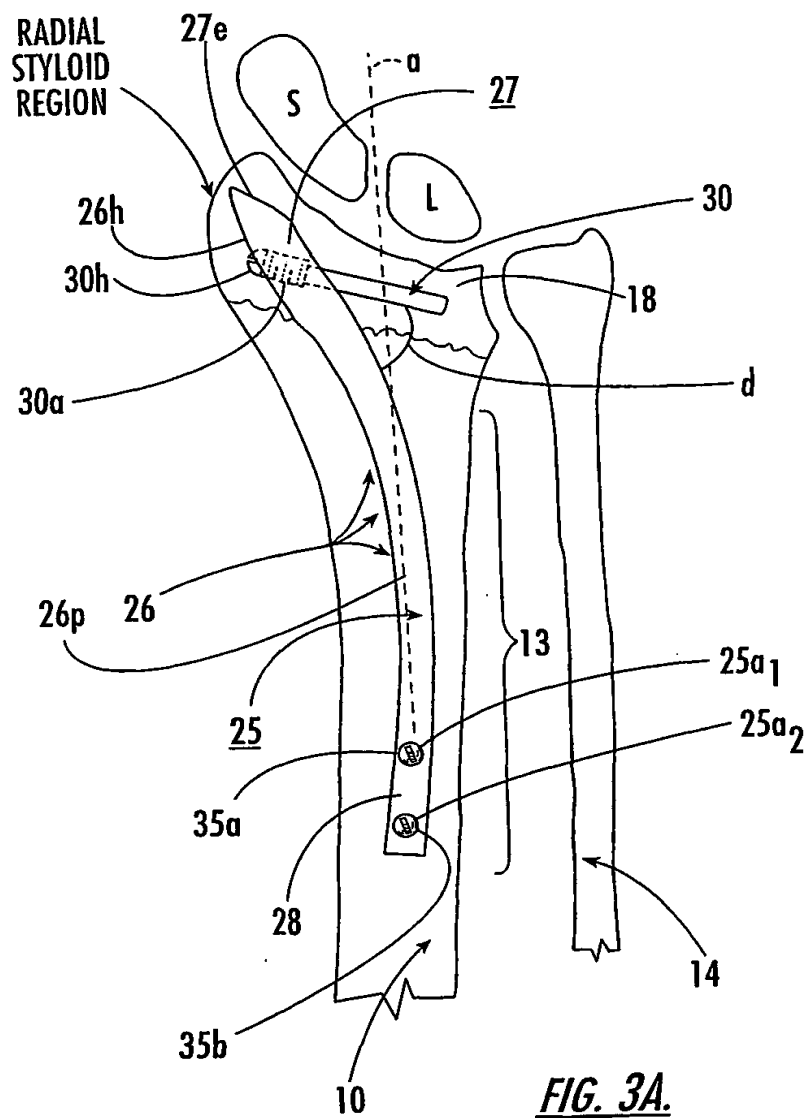
FIG. 1.

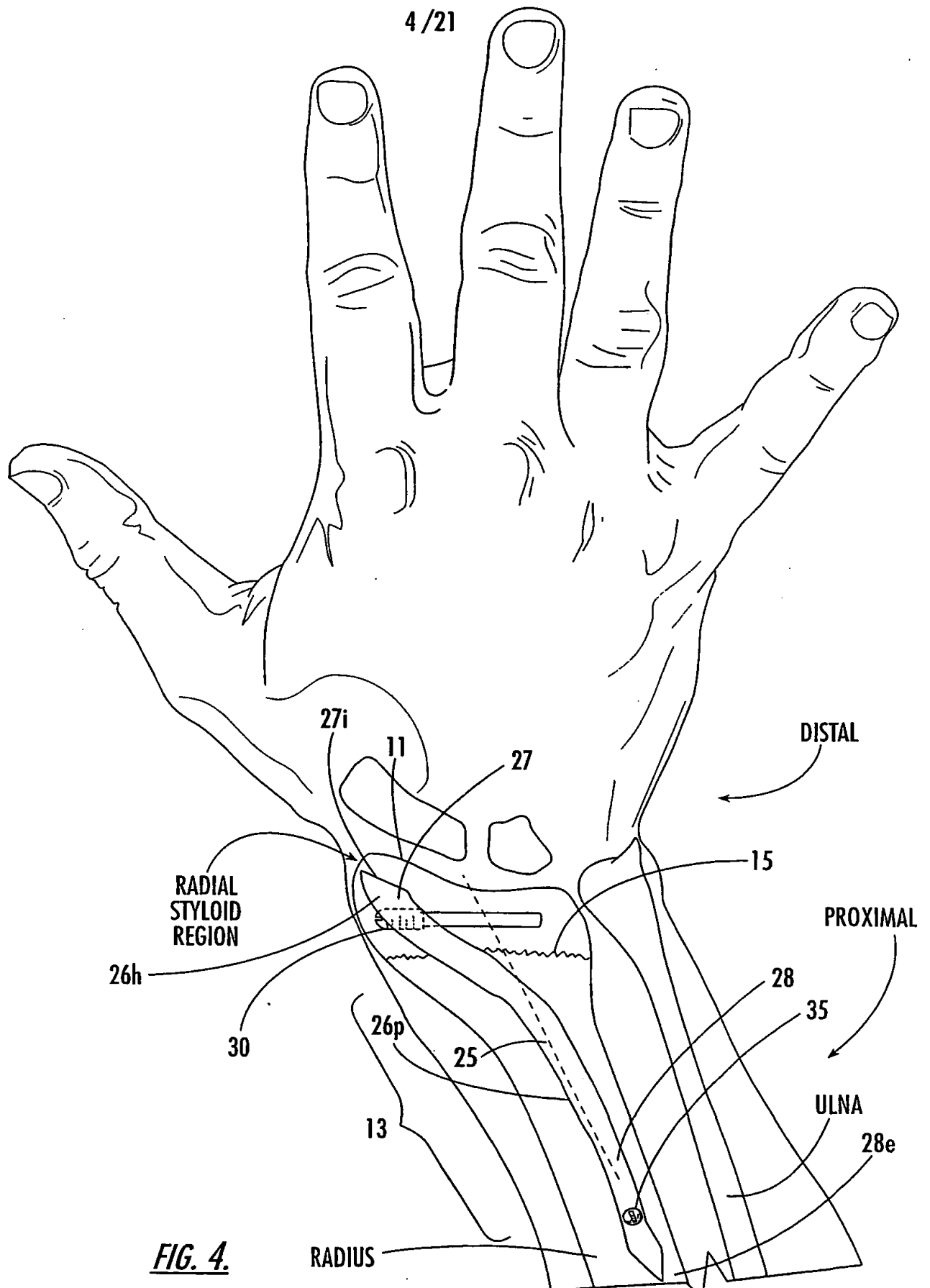
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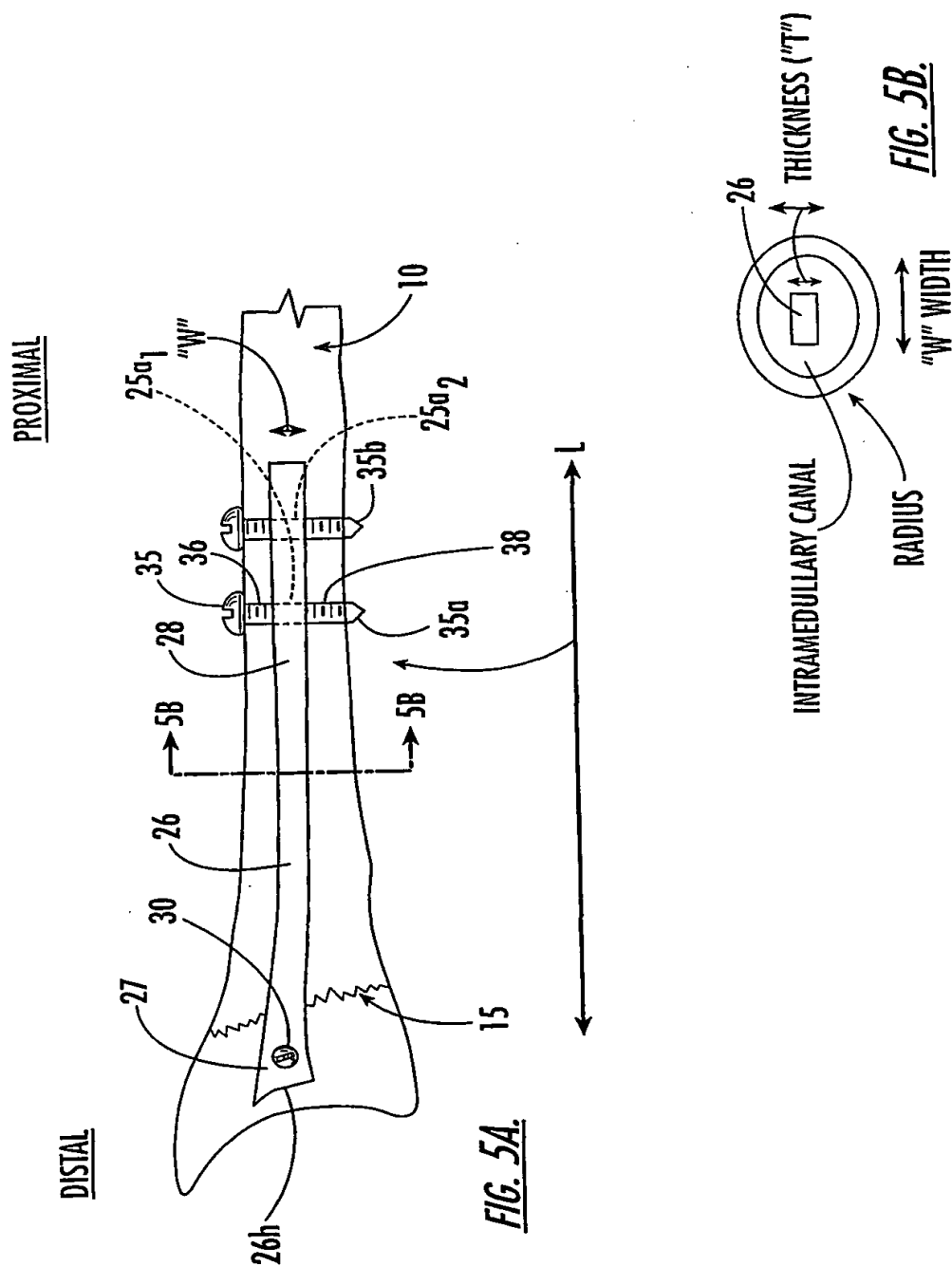


**FIG. 2.**

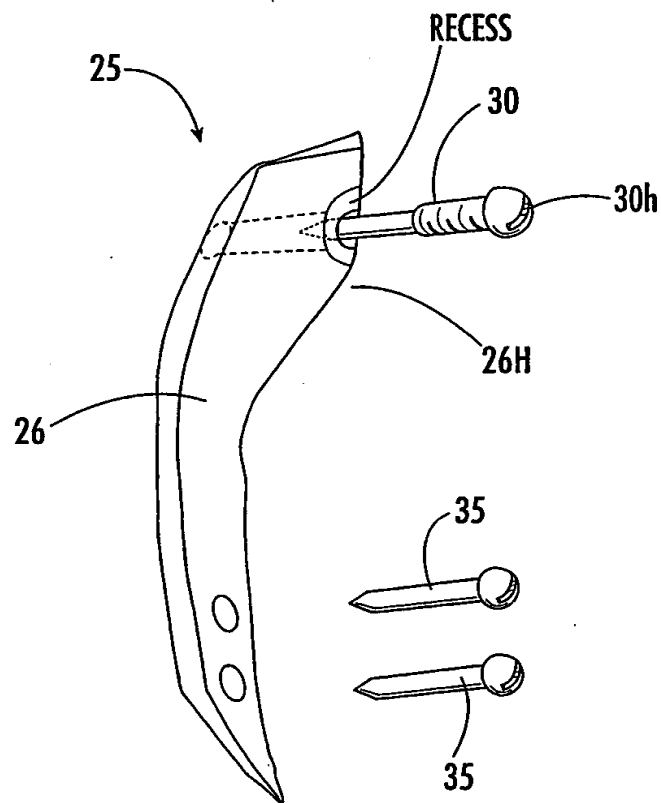
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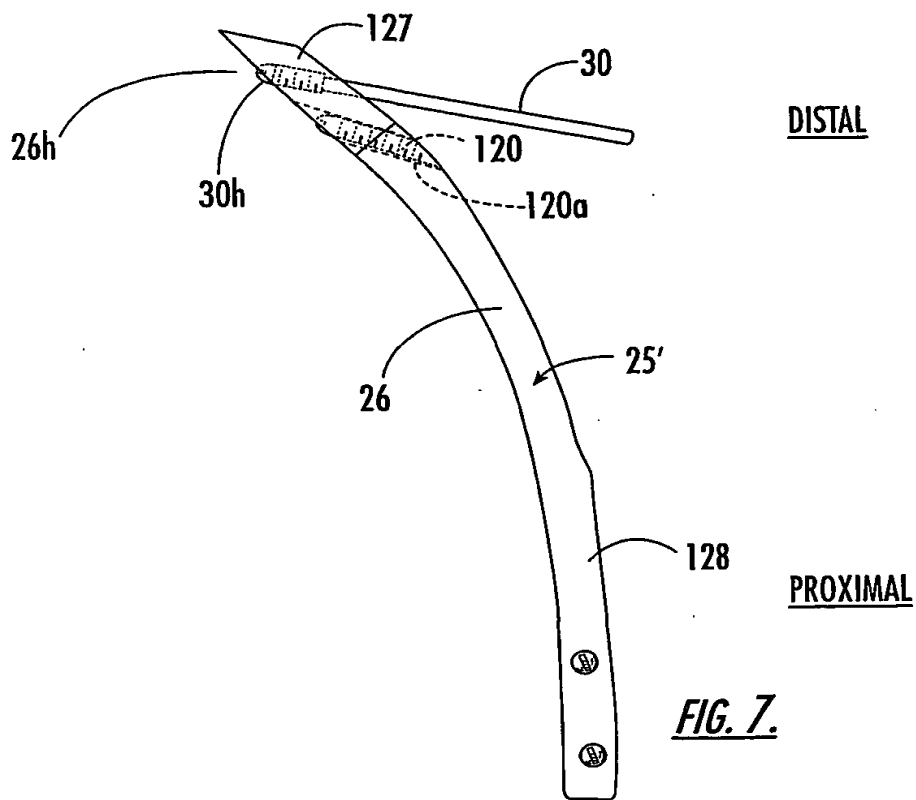
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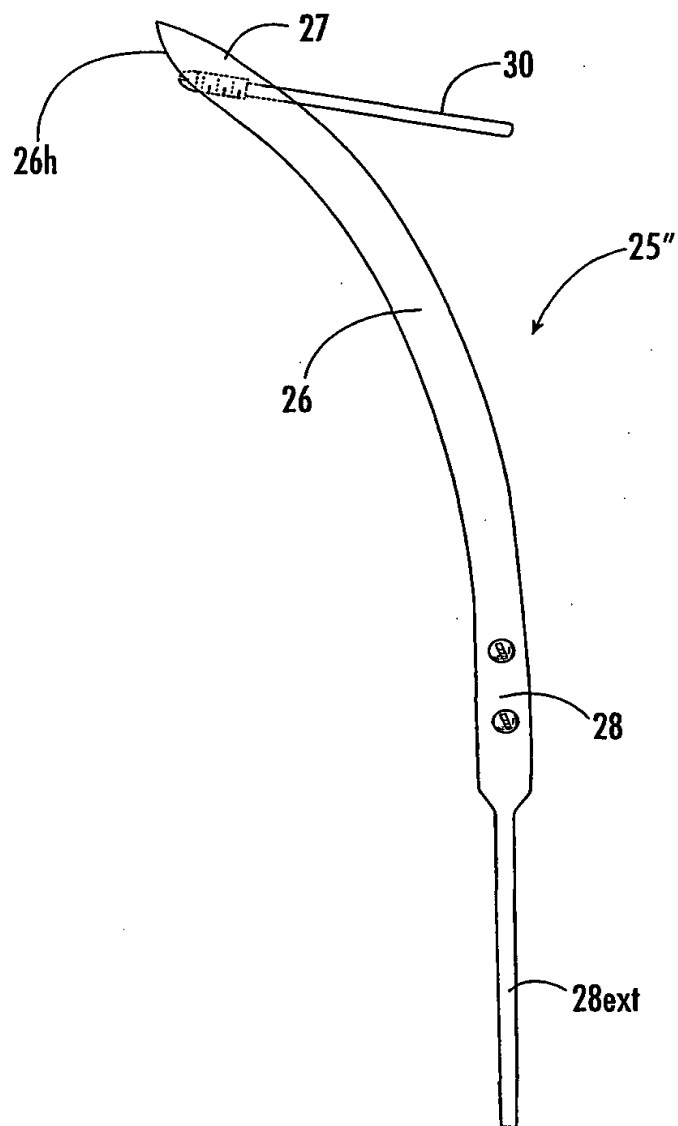
**FIG. 6.**



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**FIG. 8.**

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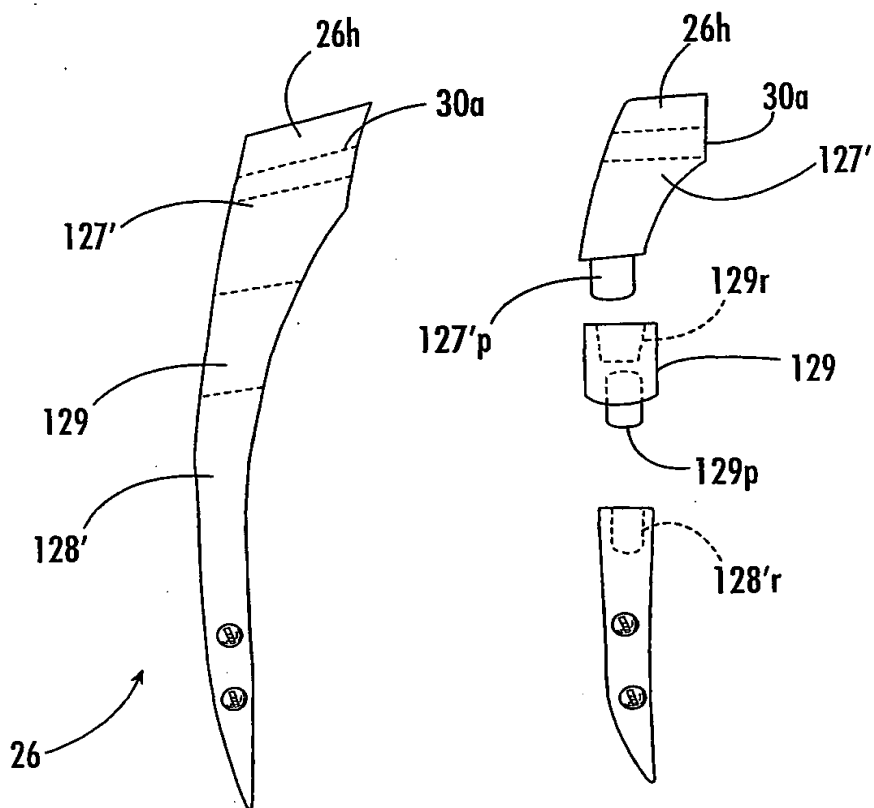


FIG. 9A.

FIG. 9B.

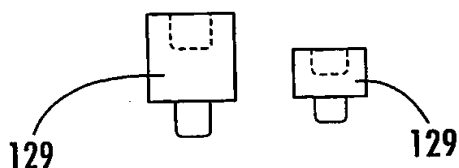


FIG. 9C.

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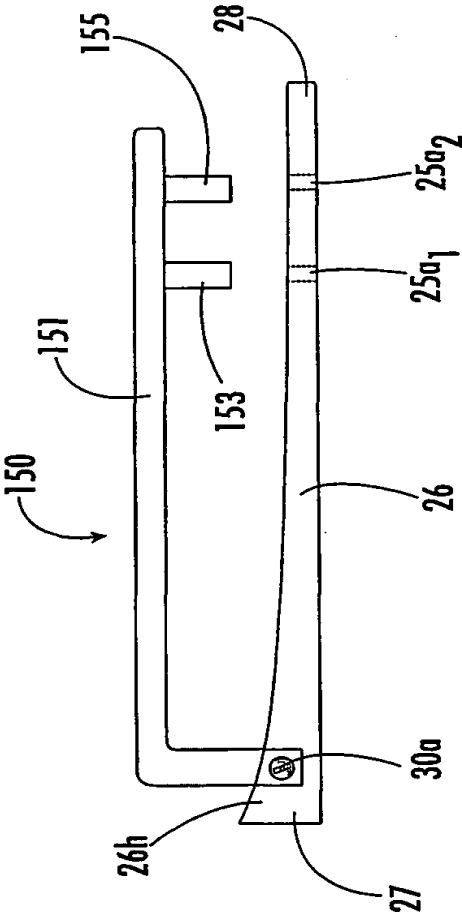
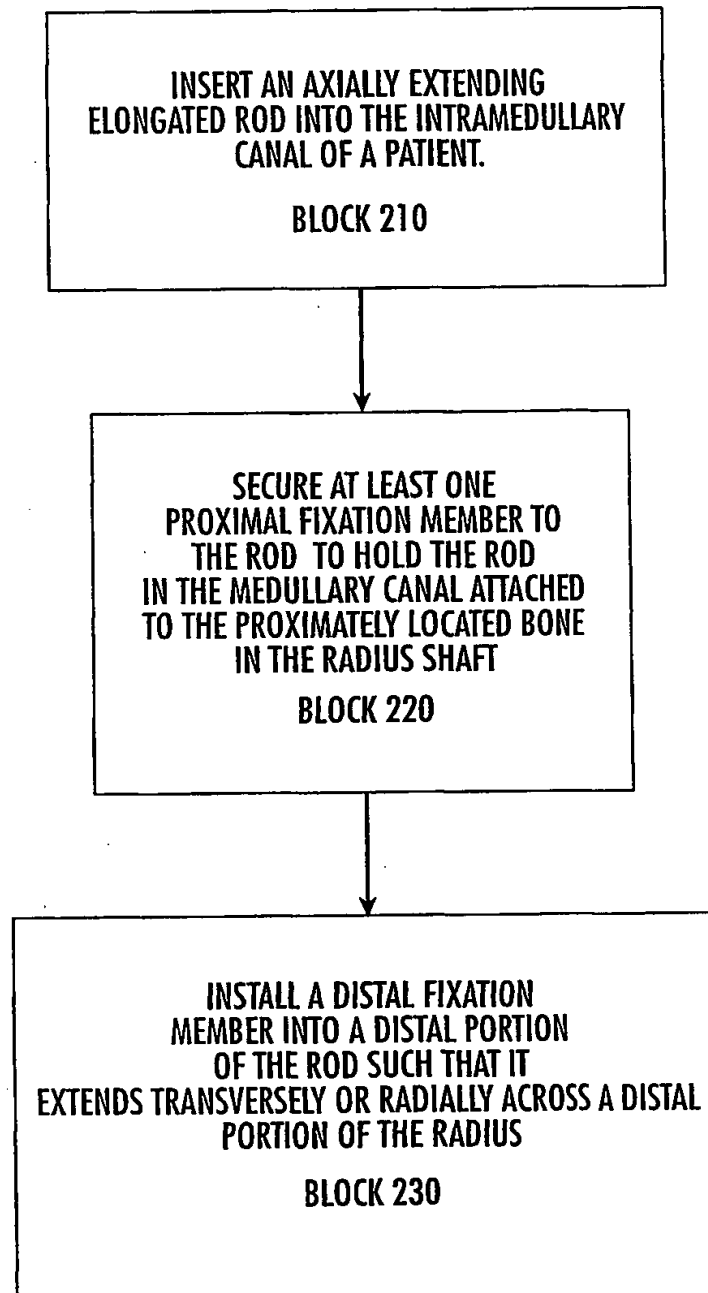


FIG. 10.

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FIG. 11.

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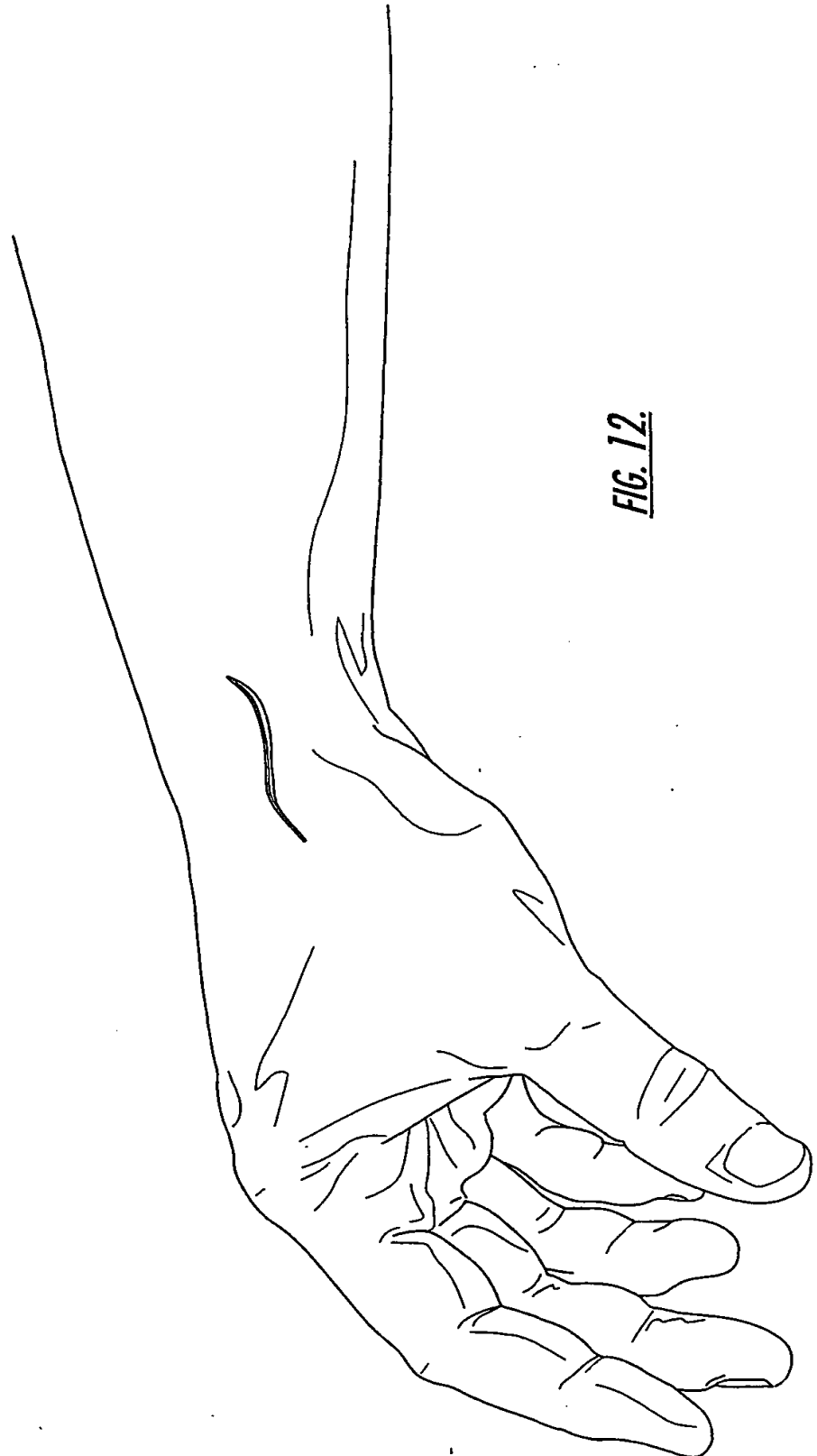
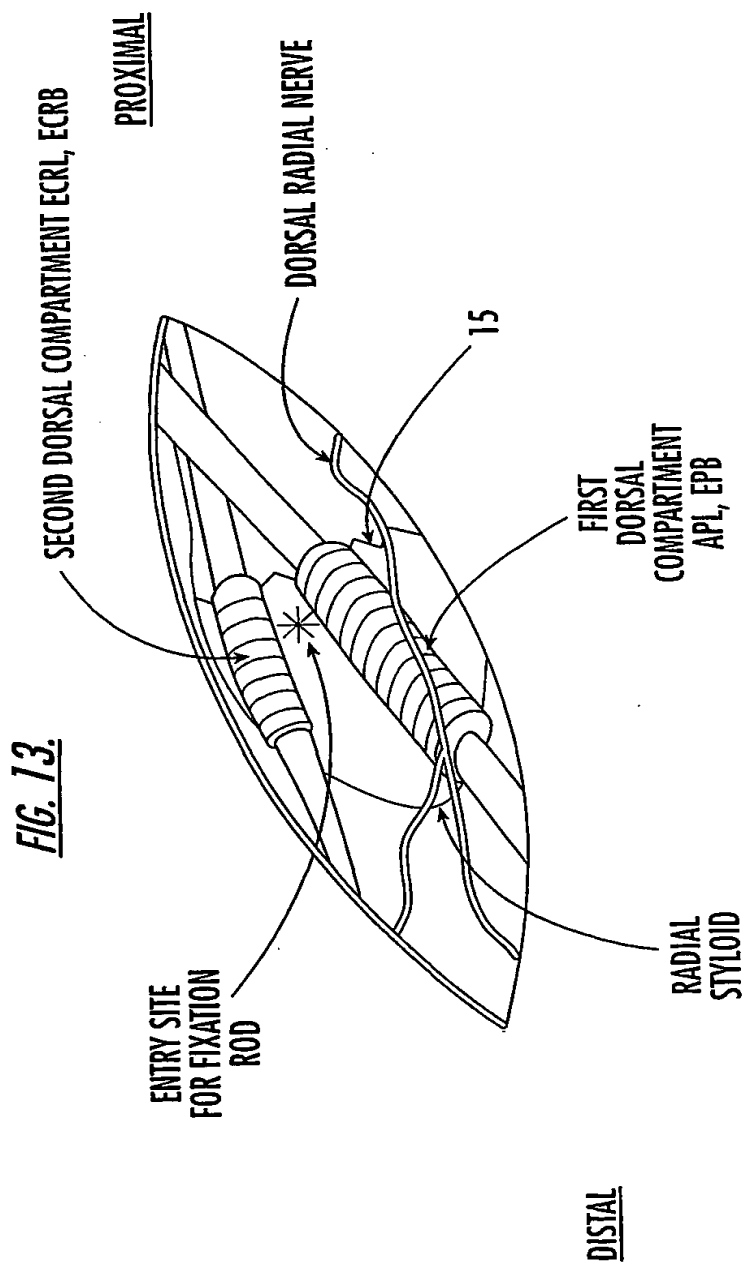
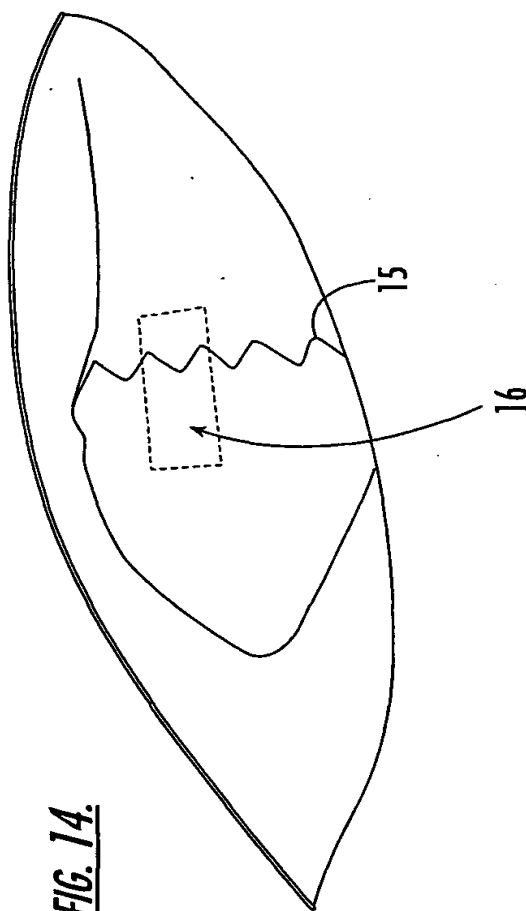


FIG. 12.

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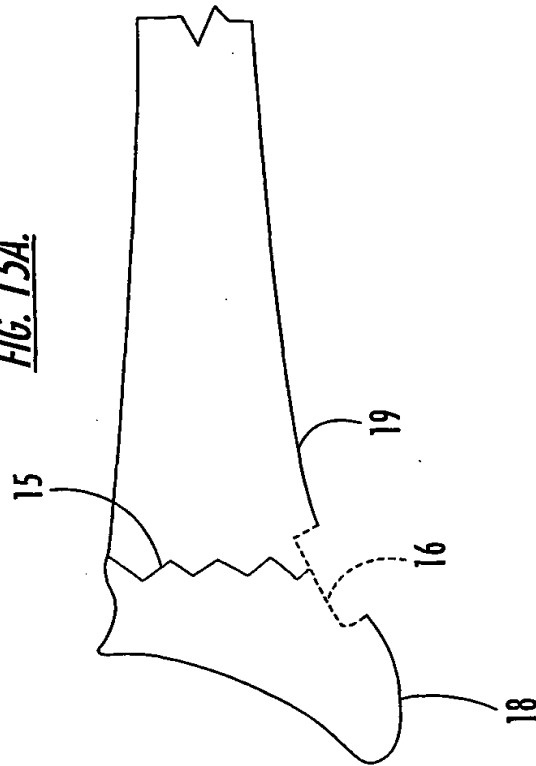
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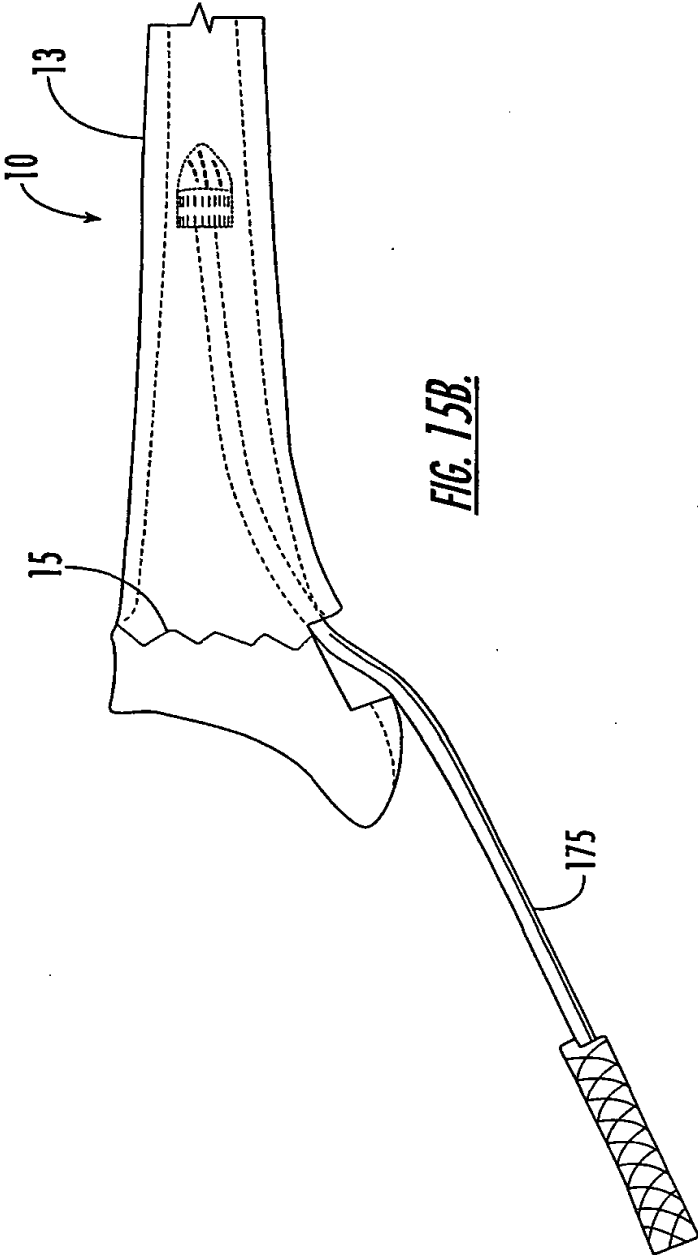




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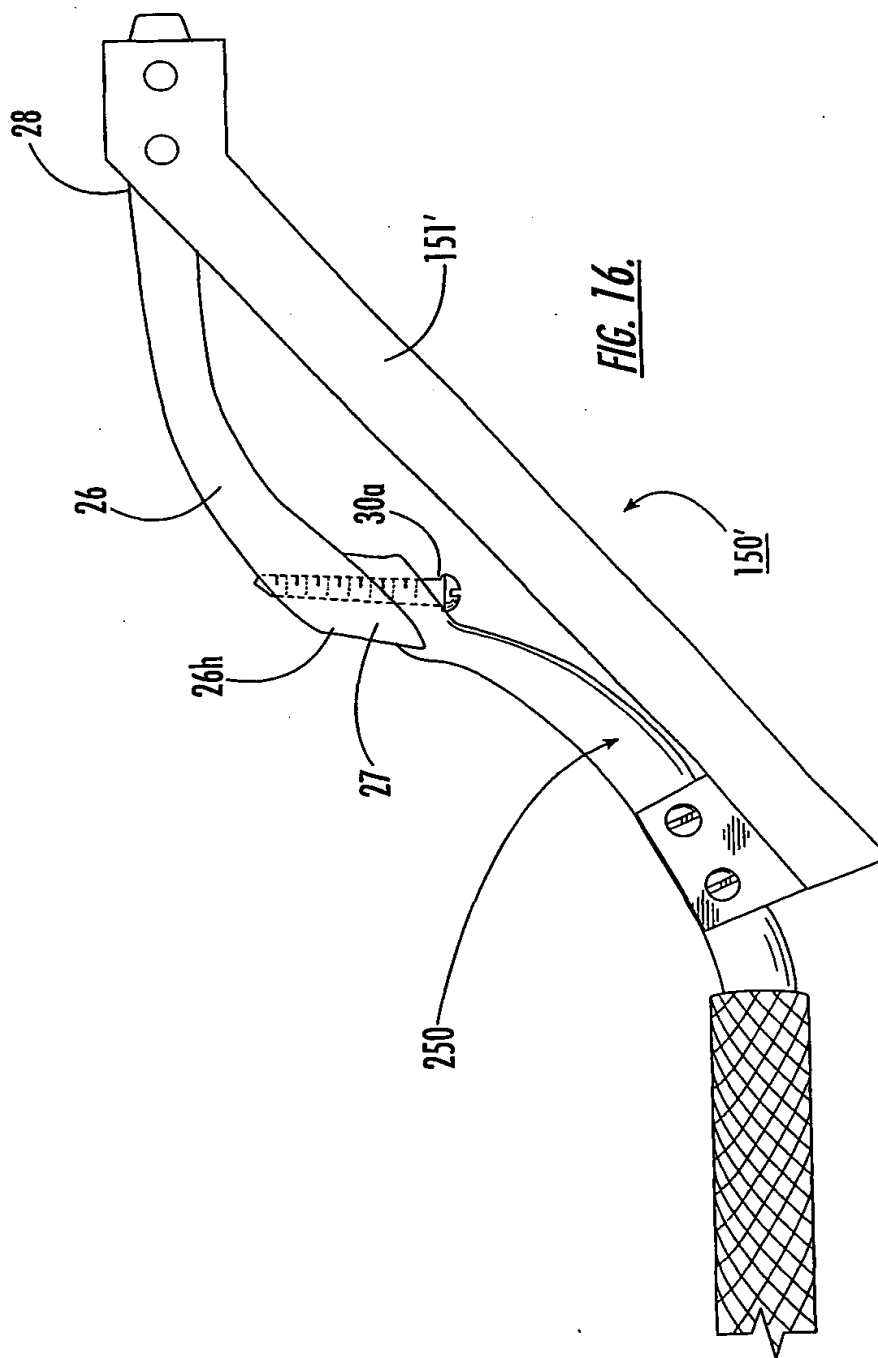
FIG. 15A.

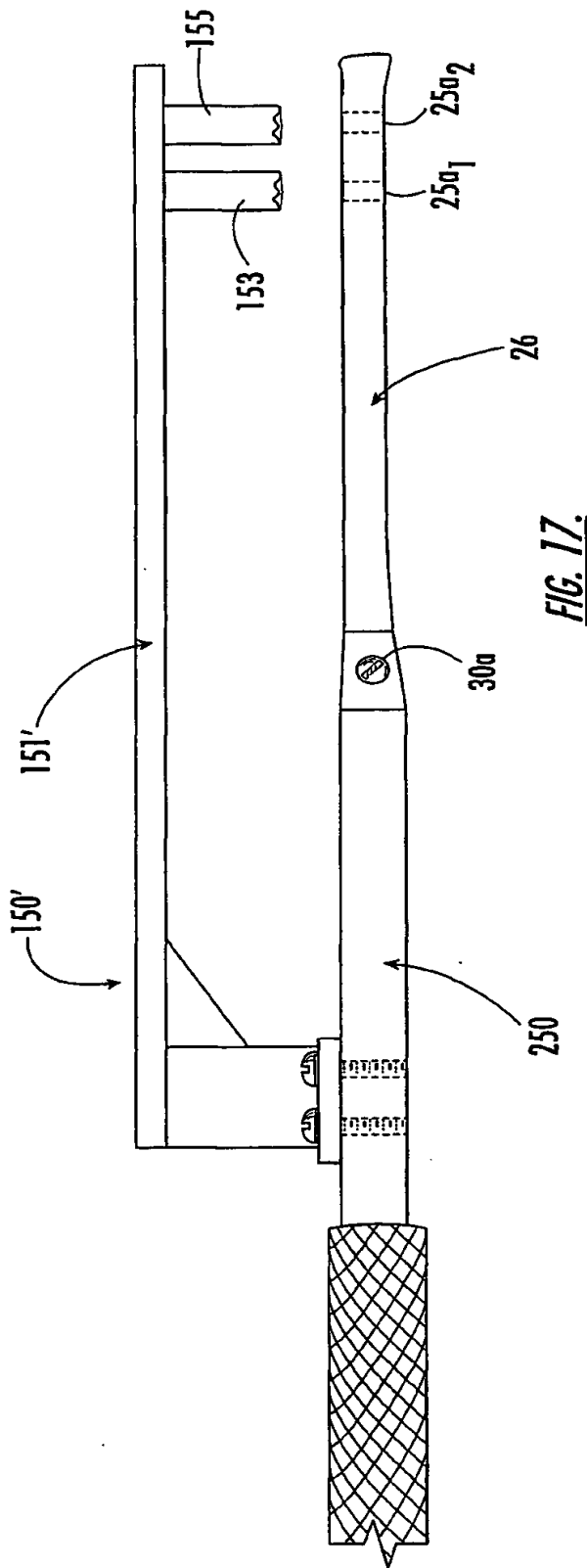


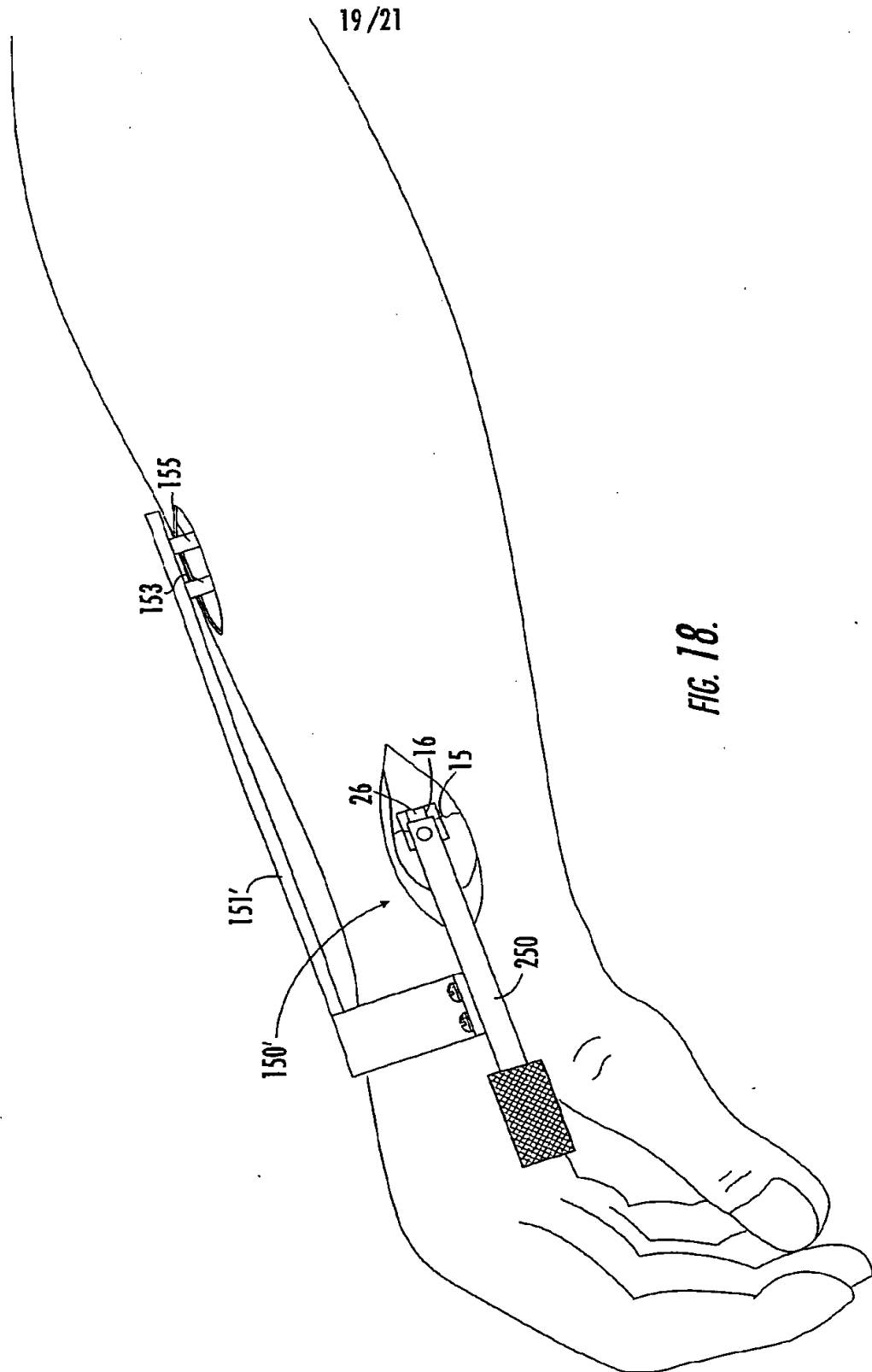


**FIG. 15B.**

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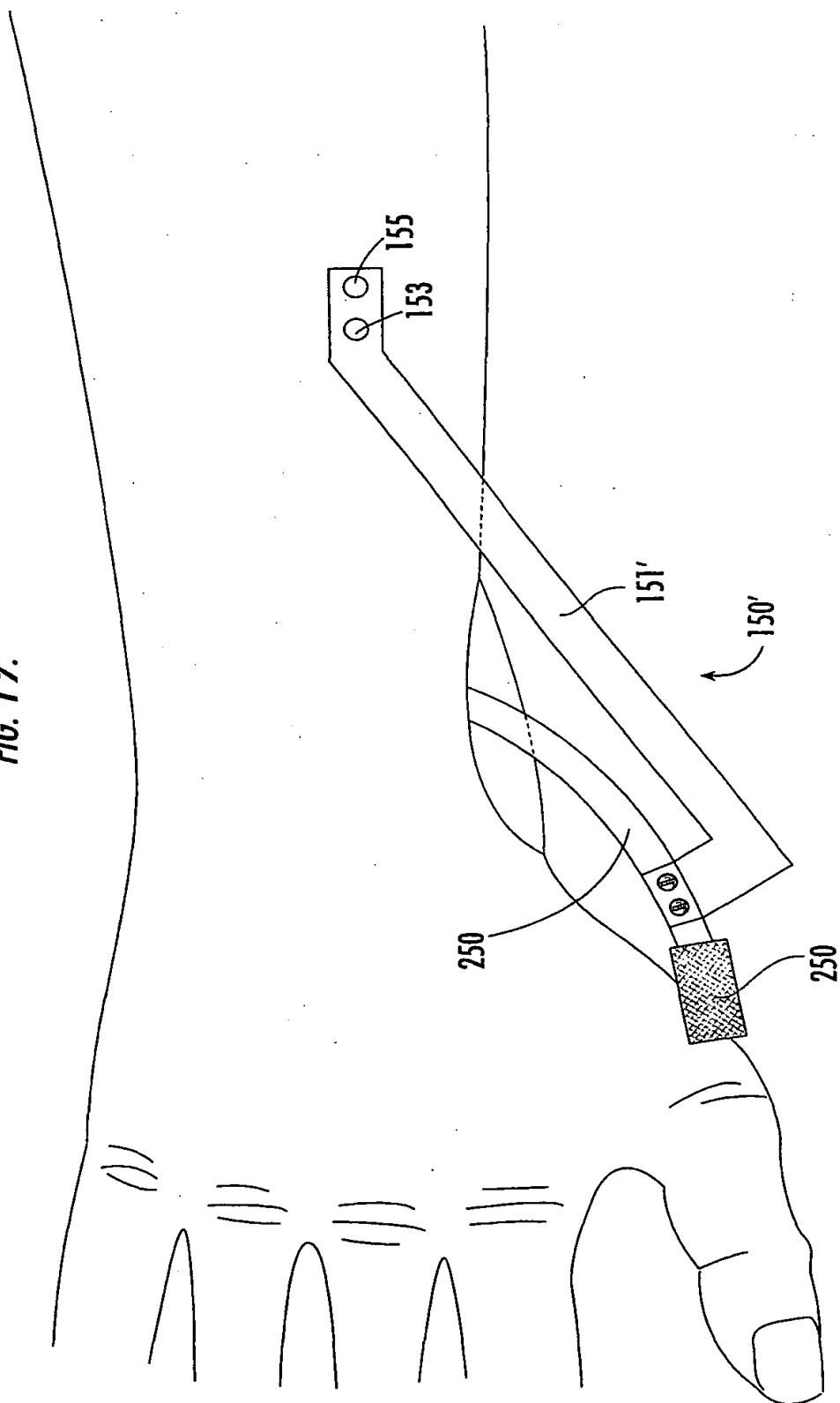






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FIG. 19.



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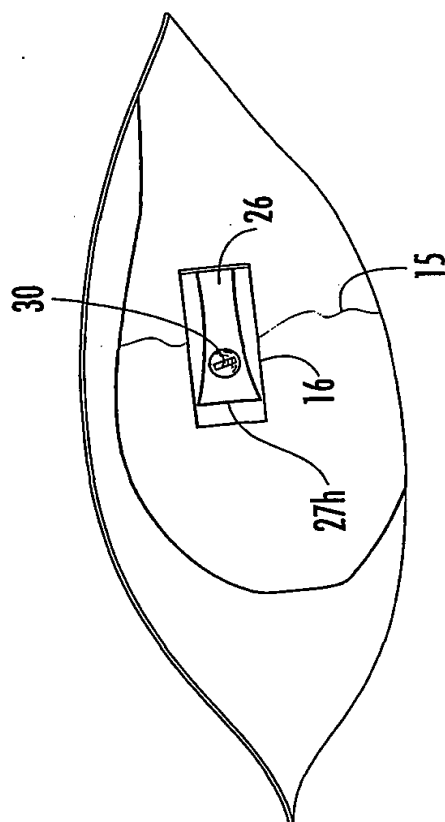


FIG. 20.

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
28 March 2002 (28.03.2002)

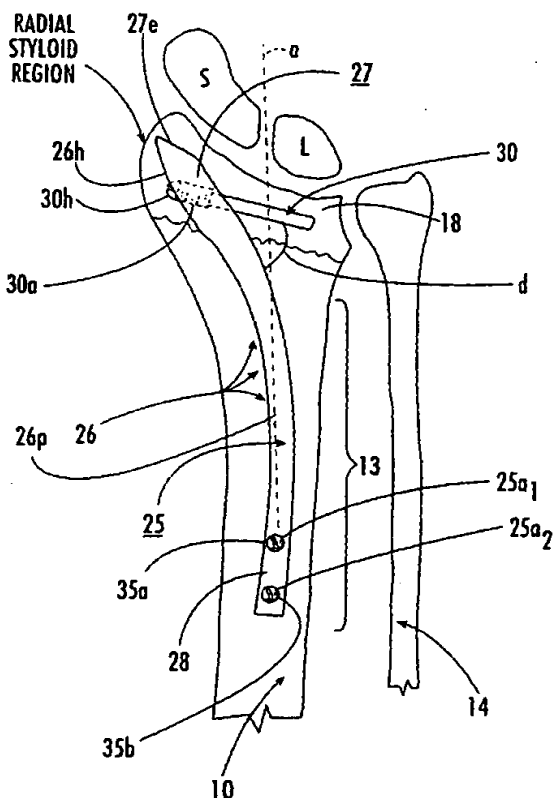
PCT

(10) International Publication Number  
**WO 02/024088 A3**

- (51) International Patent Classification<sup>7</sup>: **A61B 17/72** (74) Agent: **MYERS BIGEL SIBLEY & SAJOVEC**, P.O. Box 37428, Raleigh, NC 27627 (US).
- (21) International Application Number: **PCT/US01/27556**
- (22) International Filing Date:  
6 September 2001 (06.09.2001)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:  
09/668,941 22 September 2000 (22.09.2000) US
- (71) Applicant (for all designated States except US): **PIPER MEDICAL, INC.** [US/US]; 1036 Rockford Road, High Point, NC 27262 (US).
- (72) Inventor; and
- (75) Inventor/Applicant (for US only): **WARBURTON, Mark, J.** [US/US]; 1036 Rockford Road, High Point, NC 27262 (US).
- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: **INTRAMEDULLARY INTERLOCKING FIXATION DEVICE FOR THE DISTAL RADIUS**



(57) Abstract: Methods and devices for treating fractures in or adjacent the wrist and distal forearm employ an intramedullary interlocking fixation rod (i.e. it interlocks the distal and proximal fracture fragments together) to stabilize the skeletal structure in a manner which can inhibit the amount of collapse or loss in skeletal length exhibited by a patient with a distal radius fracture.





**Published:**

— with international search report

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

**(88) Date of publication of the international search report:**

1 August 2002

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 01/27556

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 A61B17/72

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3 709 218 A (W.X.HALLORAN) 9 January 1973 (1973-01-09)	25, 26, 30-34, 37-39, 41-43, 45
Y	column 7, line 2 - line 6; figures 4, 5, 9	27, 29, 35, 36, 40, 44, 46-50
Y	EP 0 547 380 A (HOWMEDICA) 23 June 1993 (1993-06-23)	27, 29
A	column 3, line 19 - line 22 column 4, line 17 - line 19 column 4, line 30 - line 33; figure 1 -- -/--	41

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

20 March 2002

Date of mailing of the international search report

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## INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 01/27556

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 98 18397 A (SMITH & NEPHEW) 7 May 1998 (1998-05-07) abstract; figures 1-1A,21 page 26, line 17 -page 27, line 7	35,36, 44,46-50
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